

**Consent Form
For
NSABP B-39
A Randomized Phase III Study of Conventional Whole Breast
Irradiation (WBI) Versus Partial Breast Irradiation (PBI) for
Women with Stage 0, I, or II Breast Cancer**

Sponsor: National Surgical Breast and Bowel Project (NSABP)

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Participant Initials: _____

11/02/09 This is a clinical trial, a type of research study. Your study doctor will explain the clinical trial to you. Clinical trials include only people who choose to take part. Please take your time to make your decision about taking part. You may discuss your decision with your friends and family. You can also discuss it with your health care team. If you have any questions, you can ask your study doctor for more explanation.

Why have I been asked to take part in this research study?

You are being asked to take part in this study because you have breast cancer and have had a lumpectomy to remove the cancer.

Who is conducting the study?

The National Surgical Adjuvant Breast and Bowel Project (NSABP) and the Radiation Therapy Oncology Group (RTOG) are conducting this study.

Why is this research study being done?

Studies have shown that giving radiation therapy to the breast after lumpectomy helps keep cancer from coming back in the breast. The purpose of this study is to see if partial breast irradiation (PBI) is as good as or better than whole breast irradiation (WBI) in keeping cancer from coming back in the breast. WBI is a standard treatment after a lumpectomy. WBI is radiation therapy given 5 days a week for 5 to 7 weeks to the whole breast. PBI is radiation therapy given only to the area of the breast where the cancer was removed. PBI is given 2 times a day on 5 days. PBI may be given over a period of 5 to 10 days.

03/07/11 There are 3 different methods of PBI that are being used in this study: multi-catheter brachytherapy (bray-key-THAIR-uh-pee), single-catheter brachytherapy (MammoSite[®], MammoSite[®] ML, Contura[™] MLB, and SAVI[®]), and 3D conformal external beam irradiation.

- 3-D conformal external beam irradiation uses a beam of radiation to deliver the radiation therapy dose. It is pointed to the place in your breast where the cancer was removed.
- Multi-catheter brachytherapy uses a small bead (seed) of radioactive material. The seed is passed through catheters (small, thin tubes) that are placed in the lumpectomy area. The number of tubes will depend on the size of your breast and the size of the area where the tumor had been. You will see the ends of the tubes extending from the side of your breast. The tubes will be connected to a special machine for your treatments. The radiation therapy dose is delivered by a radioactive seed as it travels through each tube. The seed will be removed at the end of each treatment. The tubes will stay in your breast until the 10 radiation therapy treatments are done.

- 03/07/11
- The MammoSite[®], MammoSite[®] ML, and Contura[™] MLB are balloon methods that use one tube with a small balloon on the end. The balloon is put in the place where the tumor had been. The balloon is filled with salt water so it fits this space. The SAVI[®] device uses a tube that has a bundle of smaller tubes inside of it that are spread open so that they fit inside the place where the tumor had been. For all of these methods, the end of the tube will extend from the side of your breast. The tube will be connected to a special machine for your treatments. The radiation therapy dose is delivered by a radioactive seed that travels through the tube into the device that has been placed in your breast. The seed will be removed at the end of each treatment. The device will stay in your breast until the 10 radiation therapy treatments are done.

These 3 PBI methods have a shorter treatment time than WBI. Early studies show that PBI may work as well as WBI. However, there has not been a study that directly compares PBI to WBI. This study will determine if the shorter PBI treatment time results in cancer returning in the breast more often than with WBI. It is also important to be sure that the way the breast looks after PBI is as good as or better than WBI.

03/30/06 This study will learn about the good and bad effects of radiation therapy. The study also will learn about the feelings women have about how their breast looks after surgery and radiation therapy.

01/08/07 **How many people will take part in the study?**

About 4,300 women will take part in the study.

What will happen if I take part in this research study?

Before you begin the study: You will need to have the following exams, tests and procedures to find out if you can be in the study. These exams, tests and procedures are part of regular cancer care and may be done even if you do not join this study. If you have had some of them recently, they may not need to be repeated. This will be up to your study doctor.

- history and physical exam
- chest x-ray or chest CT scan
- bone scan, bone x-rays, or bone tests (only if you have bone pain or if certain blood test results are not normal)
- CT scan of your abdomen (only if the blood tests related to your liver are abnormal)
- mammogram
- breast exam
- CT scan of the breast that had the cancer to help plan the radiation therapy
- blood tests (including a pregnancy test for women of childbearing potential)

During the study: If the exams, tests and procedures show that you can be in the study, and you choose to take part, then you will be "randomized" into one of the two study groups: Group 1 or Group 2. Randomization means that you are put into a group by chance. A computer program will place you in one of the study groups. Neither you nor your doctor can choose the group you will be in. You will have an equal chance of being placed in either of the two groups. Patients in Group 1 will receive WBI. Patients in Group 2 will receive PBI. Patients in both groups may receive chemotherapy and hormonal therapy if their doctor decides it is necessary.

If you are in Group 1: WBI will start soon after you join the study, if you do not need chemotherapy. If you need chemotherapy, it will be given before your radiation. Your doctor will decide which chemotherapy treatment is best for you. Your doctor will tell you about the possible side effects of the chemotherapy. After your chemotherapy is finished, you will receive WBI once a day for 5 days a week. WBI will last 5 to 7 weeks. Each treatment lasts for 10 to 15 minutes. You will visit the radiation oncology office once a day for your radiation therapy. You should be able to do most or all of your daily activities between treatments. Radiation does not stay in your body between treatments or after the final treatment.

If you are in Group 2: You will start PBI soon after you join the study. Your treatment will be given 2 times a day, about 6 hours apart, on 5 days. The treatments may be given over a period of 5 to 10 days. Each treatment lasts for 10 to 15 minutes. You will visit the radiation oncology office twice a day for your radiation therapy. You are free to leave the office and should be able to do most or all of your daily activities between treatments. Radiation does not stay in your body between treatments or after the final treatment.

03/07/11 There are 2 types of PBI at this site, but you will only receive one type. Your doctor will decide which type you can receive. If you can receive more than one type of PBI, you and your doctor will choose which type is best for you. Very rarely, treatment with single-catheter or multi-catheter brachytherapy cannot be finished. If this happens, the device will be removed. Your doctor will discuss other treatment decisions with you.

03/30/06 If you need chemotherapy, it will start after your PBI treatment is finished. Your doctor will decide which chemotherapy treatment is best for you and will tell you about the possible side effects of the chemotherapy treatment.

For both Groups 1 and 2: If your breast cancer is affected by hormones (estrogen or progesterone), your doctor will also give you at least 5 years of hormonal therapy. If you are going to receive chemotherapy, the hormonal therapy will begin after chemotherapy has ended. If chemotherapy is not going to be part of your treatment, your hormonal therapy can begin before, during, or after your radiation therapy.

03/07/11

Group 1 Standard Treatment	Group 2 Test Treatment
<p>Whole Breast Irradiation (WBI) Chemotherapy, if needed</p> <p><i>Followed by</i></p> <p>Whole Breast Irradiation <i>(1 treatment a day, 5 days a week for 5-7 weeks)</i></p>	<p>Partial Breast Irradiation (PBI)</p> <p>MammoSite[®], MammoSite[®] ML, or Contura[™] MLB Balloon Catheter or SAVI[®] Device <i>(2 treatments a day, about 6 hours apart on 5 days)*</i> <i>or</i> 3-D Conformal External Beam Irradiation <i>(2 treatments a day, about 6 hours apart on 5 days)*</i></p> <p><i>Followed by</i> Chemotherapy, if needed</p> <p>* The treatments will be given on 5 days over a period of 5 to 10 days.</p>
Group 1 and Group 2	
<p>Hormonal therapy (only if your tumor has a positive hormone receptor test) will be chosen by your doctor and will continue for at least 5 years. The timing for when the hormonal therapy will begin depends on whether or not you will receive chemotherapy.</p>	

You will need the following tests and procedures. They are part of regular cancer care unless noted otherwise.

During the first year after entering the study, you will have the following tests and procedures performed:

- *a brief history and physical exam* at the end of radiation therapy, and about 1, 6, and 12 months after finishing radiation therapy, or after finishing radiation therapy and chemotherapy, if received.
- *a mammogram and an examination of your breasts* will be performed at 6 months and 12 months after finishing radiation therapy, or after finishing radiation therapy and chemotherapy, if received.

During 2-5 years after entering the study, you will have the following tests and procedures performed:

- *a brief history and physical exam and an examination of your breasts* will be performed every 6 months after finishing radiation therapy, or after finishing radiation therapy and chemotherapy, if received.
- *a mammogram* will be performed every 12 months after finishing radiation therapy, or after finishing radiation therapy and chemotherapy, if received.

After the 5th year on the study, a brief history and physical exam, a mammogram, and an examination of your breasts will be required yearly.

How long will I be in the study?

You will be asked to visit your study doctor for follow-up exams for at least 5 years and to have yearly mammograms for the rest of your life.

We would like to keep track of your medical condition for the rest of your life. Keeping in touch with you and checking on your condition yearly helps us to look at the long-term effects of the study.

Can I stop being in the study?

Yes, you can decide to stop at any time. Tell the study doctor if you are thinking about stopping or decide to stop. He or she will tell you how to stop safely.

It is important to tell the study doctor if you are thinking about stopping so any risks from the study treatment can be evaluated by your doctor. Another reason to tell your doctor that you are thinking about stopping is to discuss what follow-up care and testing could be most helpful for you.

You can choose to withdraw one of two ways. In the first, you can stop your study treatment but still allow the study doctor to follow your care. In the second, you can stop your study treatment and not have any further contact with the study staff.

Can anyone else stop me from being in the study?

The study doctor may stop you from taking part in this study at any time if he or she believes it is in the best interest for your health, if you do not follow the study rules, or if the study is stopped by the NSABP.

What side effects or risks can I expect from being in the study?

03/30/06 You may have side effects while on this study. Most of these are listed here, but there may be other side effects that we cannot predict. Side effects will vary from person to person. Everyone taking part in the study will be carefully watched for any side effects. However, doctors do not know all the side effects that may happen. Side effects may be mild or very serious. Your health care team may give you medications to help lessen some of the side effects. Many side effects go away soon after your radiation therapy. In some cases, side effects may be very serious, long-lasting, or may never go away.

You should talk with your study doctor about any side effects that you may have while taking part in the study.

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03/07/11 ***Risks and side effects related to single-catheter brachytherapy methods of PBI (MammoSite[®], MammoSite[®] ML, Contura[™] MLB, SAVI[®])***

Likely effects

03/07/11 These side effects occur in **10% or more** of patients receiving radiation therapy with single-catheter brachytherapy methods:

- mild redness of the skin over the area of the balloon
- mild scar tissue
- flaking or peeling of dry skin over the area of the balloon
- slightly smaller breast size or change in the way the breast looks
- swelling of the breast
- bruising
- mild breast pain

Less likely effects

03/07/11 These side effects occur in **3-9%** of patients receiving radiation therapy with the single-catheter brachytherapy methods:

- infection
- small visible blood vessels on the skin surface over the area of the balloon
- increased firmness of the breast tissue
- slight change in color of the skin over the area of the balloon
- thickening of the skin over the area of the balloon
- 03/30/06 • damaged fat cells in the breast that cause a red, swollen, or tender area in the breast (These damaged cells may look like a tumor and a biopsy may be needed.)

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- catheter may have to be reinserted under local anesthesia

Rare but serious effects

03/07/11 These side effects are **rare but serious**, occurring in less than **3%** of patients receiving radiation therapy with single-catheter brachytherapy methods:

- severe scar tissue
- severe infection
- breast pain lasting a long time
- 03/30/06 • another cancer due to radiation therapy

Risks and side effects related to whole breast irradiation (WBI) or 3-D conformal external beam PBI

Likely effects

These side effects occur in **10% or more** of patients receiving whole breast or 3-D conformal external beam radiation therapy:

- reddening of the skin during treatment and for several weeks following treatment
- tanning of the skin lasting months and may be permanent
- slightly smaller breast size or change in the way the breast looks
- tiredness and weakness during treatment and for several weeks following treatment
- muscles in chest wall under treated breast may feel tight or sore
- swelling of breast

Less likely effects

These side effects occur in **3-9%** of patients receiving whole breast or 3-D conformal external beam radiation therapy:

- peeling of the skin in the area treated with radiation
- pain at the site of radiation treatment

Rare but serious effects

These side effects are **rare but serious**, occurring in less than **3%** of patients receiving whole breast or 3-D conformal external beam radiation therapy:

- cough
- difficulty breathing
- irritation of the sac surrounding the heart
- inflammation of the heart muscle
- rib fracture
- 03/30/06 • another cancer due to radiation therapy

Risk related to fertility and pregnancy: If you are pregnant, you should not take part in this study. You should not become pregnant if you decide to take part because the radiation can

affect an unborn baby. Ask for more information about preventing pregnancy if this applies to you. Also, you should not nurse your baby while on this study. Ask your doctor for more information.

For more information about risks and side effects, ask your study doctor.

Are there benefits to taking part in this study?

Taking part in this study may or may not make your health better. While doctors hope that PBI will be at least as effective in preventing breast cancer from returning as WBI, there is no proof of this yet. We do know that the information from this study will help doctors learn more about PBI as a treatment for breast cancer. This information could help future cancer patients.

What other choices do I have if I do not take part in this study?

Your other choices may include:

- 03/30/06
- Receiving WBI or PBI without being in this study
 - Getting treatment or care for your cancer without being in this study
 - Taking part in another study
 - Getting no treatment

Please talk with your doctor about your choices before you decide if you will take part in this study.

11/02/09 **Will my medical information be kept private?**

We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Organizations that may look at and/or copy your medical records for research, for quality assurance, and data analysis include:

- the National Surgical Adjuvant Breast and Bowel Project (NSABP);
- the Radiation Therapy Oncology Group (RTOG);
- a local Institutional Review Board (IRB), a group of people who review the research study to protect your rights; Liberty IRB (Institutional Review Board)
- the Cancer Trials Support Unit (CTSU), a research group sponsored by the National Cancer Institute (NCI) to provide greater access to cancer trials; and
- government agencies, including the NCI or its authorized representatives, the FDA, the Office for Human Research Protections (OHRP), Health Canada, and the Irish Medicines Board. These agencies may review the research to see that it is being done safely and correctly.
- NCI CIRB (National Cancer Institute Central Institutional Review Board), a group of people who review the research study to protect your rights

03/30/06 **What are the costs of taking part in this study?**

You and/or your health plan/insurance company will need to pay for all of the costs of treating your cancer in this study. Some health plans will not pay these costs for people taking part in studies. Check with your health plan or insurance company to find out what they will pay for. Taking part in this study may or may not cost your insurance company more than the cost of getting regular cancer treatment.

You will not be paid for taking part in this study.

For more information on clinical trials and insurance coverage, you can visit the National Cancer Institute's Web site at <http://cancer.gov/clinicaltrials/understanding/insurance-coverage>. You can print a copy of the "Clinical Trials and Insurance Coverage" information from this Web site. Another way to get the information is to call 1-800-4-CANCER (1-800-422-6237) and ask them to send you a free copy.

What happens if I am injured because I took part in this study?

It is important that you tell your study doctor, _____, if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call him or her at (386)254-4212 (a 24 hour number)..

You will get medical treatment if you are injured as a result of taking part in this study. You and/or your health plan will be charged for this treatment. The study will not pay for medical treatment.

What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

The Data Monitoring Committee (DMC), an independent group of experts, will be reviewing the data from this research throughout the study. We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study. You may be asked to sign another consent form in response to new information.

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

Who can answer my questions about the study?

You can talk to Dr. Deveras, the Principal Investigator overseeing the study at Halifax Health or your Study Doctor as listed on page one of this consent regarding any questions or concerns you have about this study. You can contact them at:

Halifax Health
Center for Oncology
303 N. Clyde Morris Blvd.
Daytona Beach, FL 32114
(386) 254-4212 (24-Hour Number)

If you have any questions about your rights as a participant in this research study, you can contact

Liberty IRB, Inc.
2024 Larchmont Drive
DeLand, Florida 32724
(386) 740-9278 (Business Hours)

The Liberty Institutional Review Board (IRB) approves research conducted at Halifax Health and is a committee that has reviewed this research study to help ensure that your rights and welfare as a research participant are protected and that the research study is carried out in an ethical manner.

You may also call the Operations Office of the NCI Central Institutional Review Board (CIRB) at 888-657-3711 (from the continental US only)

Additional tests for the NSABP B-39/RTOG 0413 study

The following section of the informed consent form is about additional research studies that may be done with people who are taking part in the main study. You may take part in these additional studies if you want to. You can still be part of the main study even if you say "no" to taking part in these additional studies.

Consent for use of blood and tissue for future research

About using blood and tissue for future research: The NSABP would like to keep some of the blood and tissue that is taken during the study but is not used for other tests. If you agree, the blood and tissue samples will be kept and may be used in future research to learn more about cancer and other diseases. The blood and tissue samples will be given only to researchers approved by the NSABP. Any research study using your samples must also be approved by an IRB. The research that is done with your blood and tissue samples is not designed to specifically help you. It might help people who have cancer and other diseases in the future. Reports about research done with your samples will not be given to you or your doctor. These reports will not be put in your health records. The research using your blood and tissue samples will not affect your care.

Things to think about: The choice to let the NSABP keep the blood and tissue samples for future research is up to you. No matter what you decide to do, it will not affect your care in this study. If you decide now that your blood and tissue samples can be kept for research, you can change

your mind at any time. Just contact your study doctor and let him or her know that you do not want the NSABP to use your blood and tissue samples and they will no longer be used for research. Otherwise, they may be kept until they are used up, or until the NSABP decides to destroy them.

In the future, people who do research with your blood and tissue samples and people who do other types of health-related research may need to know more about your health. While the NSABP may give them reports about your health, they will not give them your name, address, phone number, or any other information that will let the researchers know who you are.

Sometimes blood and tissue samples are used for genetic research (about diseases that are passed on in families). Even if your blood and tissue samples are used for this kind of research, the results will not be told to you and will not be put in your health records.

Your blood and tissue samples will only be used for research and will not be sold. The research done with your samples may help to develop new products in the future, but you will not get paid.

Benefits and risks: The possible benefits of research from your blood and tissue include learning more about what causes cancer and other diseases, how to prevent them and how to treat them. The greatest risk to you is the release of information from your health records. The NSABP will protect your records so that your name, address, and phone number will be kept private. The chance that this information will be given to someone else is very small. There will be no cost to you for any blood and tissue collected and stored by the NSABP.

Making your choice: Please read each sentence below and think about your choice. After reading each sentence, mark "Yes" or "No". If you have questions, please talk to your doctor or nurse. Remember, no matter what you decide to do about the storage and use of your blood and tissue samples, you may still take part in the B-39/0413 study.

Indicate your choices by marking "Yes" or "No" after each statement.

1. My blood and tissue samples may be kept by the NSABP for use in future research to learn about, prevent, detect, or treat cancer.

YES _____ NO _____ Participant's Initials _____

2. My blood and tissue samples may be used for research about other health problems (for example: causes of heart disease, osteoporosis, diabetes).

YES _____ NO _____ Participant's Initials _____

3. My study doctor (or someone he or she chooses) may contact me in the future to ask me to take part in more research.

YES _____ NO _____ Particiapnt's Initials _____

Where can I get more information?

- You may call the National Cancer Institute's (NCI's) Cancer Information Service at:
1-800-4-CANCER (1-800-422-6237) or TTY: 1-800-332-8615

You may also visit the NCI Web Site at <http://cancer.gov>

For the NCI's clinical trials information, go to: <http://cancer.gov/clinicaltrials>

For the NCI's general information about cancer, go to: <http://cancer.gov/cancerinfo>

You may also visit the NSABP Web site at <http://www.nsabp.pitt.edu>

You will receive a copy of this form. If you want more information about this study, ask your study doctor.

Signatures

I have been given a copy of all 12 pages of this form. I have read the consent form or it has been read to me. This information was explained to me and my questions were answered.

I agree to take part in this research study.

Participant's Printed Name

Participant's Signature

Date

Time

Printed Name of Person Conducting Informed Consent Discussion

**Signature of Person
Conducting Informed Consent Discussion**

Date

Time

Physician's Printed Name

Physician's Signature

Date

Time